



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/522,013

10/07/2005

James H Heller

000250.00029

5202

22907 7590 12/09/2008

BANNER & WITCOFF, LTD.

1100 13th STREET, N.W.

SUITE 1200

WASHINGTON, DC 20005-4051

EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/522,013 | Applicant(s) HELLER ET AL. | |
| | Examiner MARCOS SZNAIDMAN | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-40 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 16, 23-40 and 49-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 page / 08/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on August 12 and August 18, 2008.

Priority

The present application is a 371 of PCT/US03/22746 filed on 07/22/2003, and claims priority to provisional application No. 60/397,123 filed on 07/22/2002.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (Maintained Rejection)

Claims 1-8, 10-12, 16 and 23-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (US 6,458,807, cited in prior office action).

The reasons for this rejection have been provided in the previous office action dated February 21, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Art Unit: 1612

Applicant argues that the patient population described by Pratt (US 6,458,807, cited in prior office action) is not the same as the instant application because Pratt is directed to treating individuals with acquired condition (i.e., something acquired later in life due to a disease or medical event). Acquired learning problems are not specific learning disabilities.

Examiner response is: although is true that Pratt et. al. teach the treatment of cognitive impairments, which by definition it refers to an acquired deficit in one or more of memory function, problem solving, orientation and/or abstraction that impinges on an individual's ability to function independently (see column 4, lines 42-45), it is also true that Pratt et. al. teach a novel method for treating and preventing apathy by administering to a patient a therapeutically effective amount of at least one of the cholinesterase inhibitor compounds described herein (see column 4, lines 6-10). The authors define "apathy" as a slowing of cognitive processes and/or lack of motivation manifested by one or more of the following: lack of productivity, lack of initiative, lack of perseverance, diminished socialization or recreation, lack of interest in learning new things, etc (see column 9, lines 15-19). Pratt et. al. also teach a novel method for enhancing cognitive functions by administering to a patient a therapeutically effective amount of at least one of the cholinesterase inhibitor compounds described herein (see column 4, lines 15-19). The authors define "enhancing cognitive functions" as to increasing or improving a patient's normal level of cognitive functioning, including, for example, learning and recall of newly learned information (see column 9, lines 23-26).

Art Unit: 1612

It is obvious from the last two examples: treating or preventing apathy and enhancing cognitive functions, that the populations encompass or at least overlap with the population being treated by the instant application, since none of the populations described above by Pratt et. al. comprises individuals with acquired conditions. The population comprises normal individuals that happen to have specific learning problems that are not the result of visual, hearing, motor disabilities, mental retardation, emotional disturbance, etc. It is also obvious that “treating the slowing of a cognitive process”, or “enhancing cognitive functions” and “improving the ability of an individual to learn and recall newly learned information” encompass improving “language information processing and learning” in an individual.

Rejection of claim 16 was modified as follows: Claim 16 teaches the same limitations as claim 12, wherein the dose of donepezil is 1 to 10 mg/day.

For claim 16, Pratt et. al. further teach that the cholinesterase inhibitors, and donepezil in particular can be administered in doses of about 5 mg/day or 10 mg/day (see column 20, lines 4-8)

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to administer an individual in need thereof donepezil within the dose range described in claim 16 based on the teachings of Pratt et. al., thus resulting in the practice of claim 16 with a reasonable expectation of success.

***Claim Rejections - 35 USC § 103 (a) (New Rejection, Necessitated by
Amendment)***

Claims 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (US 6,458,807, cited in prior office action) as applied to claims 1-8, 10-12, 16 and 23-40 above, and further in view of Ripich et. al. (Neurology (1997) 48:781-783) or Sanger et. al. (J. Commun. Disord. (2000) 33:31-57).

Pratt et. al. teach all the limitations of claims 49-54, except for monitoring the efficacy of said dose by objectively measuring language performance. However, Ripich et. al. teach that the Test of Problem Solving (TOSP) is a standard test to assess higher level cognitive skills in response to problem-solving questions (see abstract) and Sanger et. al. teach that Clinical Evaluation of language Fundamentals is commonly used to test communication behaviors (see abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to further test the progress of a learning or language treatment, with the motivation of improving the results of the drug treatment, thus resulting in the practice of claims 49-54, with a reasonable expectation of success.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1612

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
November 18, 2008

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612